

Remarks

This Reply is responsive to the office action mailed on March 18, 2009. Claims 1-3, 5-22, and 24-33 are pending in the application. Claims 1, 5-10, 12-22, 24, 28-30, and 32 have been amended, and claims 2, 11, 25, and 33 have been canceled. No new matter has been introduced. Applicants respectfully request reconsideration of the pending claims in view of the foregoing amendments and following remarks.

Claim Rejections - 35 USC § 102

Claim 24 stands rejected under 35 U.S.C. §102(b) as being anticipated by Bonsignore et al. (U.S. Published Application No. 2004/0186555).

Claim 24 has been amended to recite a stent with a main body defining a plurality of cells, the main body having opposite ends, and a plurality of cantilever members extending from the main body substantially parallel to a longitudinal axis of the main body in a radially-collapsed orientation and extending radially outward in a flared configuration. The cantilever members have each a radially thinned section proximate an attachment location to the main body, wherein the radially thinned section defines a bend location, at which the cantilever members transition from the radially-collapsed orientation to the flared configuration.

Bonsignore describes in FIG. 8 in a cross-sectional view a marker housing 802. The thickness of marker 804 appears to be less than the thickness of the housing 802. When the stent expands, these markers remain substantially parallel to a longitudinal axis of the main body and do not extend radially outward in a flared configuration. Moreover, even if the markers were regarded as the radially thinned sections, the thin portion of the marker does not define a bend location, at which the cantilever members transition from the radially-collapsed orientation to the flared configuration. Applicant also wishes to point out, although this issue was not raised by the examiner, that the housing 802 of the radiopaque marker is attached to the stent body 100 by small connecting links (not labeled) which are narrower than the housing 802 and the struts of the stent 100 in the circumferential direction, without being radially thinned, as claimed in claim 24.

Applicant therefore submits that claim 24, as amended herein, is not anticipated by Bonsignore. Withdrawal of this rejection is therefore respectfully requested.

Claim Rejections - 35 USC § 103

Claims 1, 14, 18, 24, 28 and 30 are the independent claims.

Claims 1-3, 5-17, 25-26, and 28-31 are rejected under 35 U.S.C. §103(a) as being unpatentable over Phelps et al. (U.S. Pat. No. 6,290,728; hereinafter “Phelps”) in view of Shanley (U.S. Pat. No. 6,241,762; hereinafter “Shanley”).

Regarding the rejection of claims 1, 14, 28 and 30 as being unpatentable over Phelps in view of Shanley, claim 1, as amended herein, recites a stent with a main body which defines a longitudinal axis and a radial direction and includes a plurality of support members extending about a circumference of the main body and defining a plurality of cells, the main body including opposite ends. The stent further includes an end structure including a plurality of cantilever members, wherein each cantilever member has a base end coupled with one of the ends of the main body and a second opposing free end and wherein each cantilever member is movable from a longitudinal orientation in alignment with the longitudinal axis of the main body to a flared position projecting radially outwardly from the main body. The corresponding base end of each cantilever member is connected to the main body at a predefined bend location having a reduced radial wall thickness at the bend location, with the cantilever member transitioning at the bend location from the longitudinal orientation to the flared position upon flaring of the end structure relative to the main body. Claims 14, 18, 24, 28 and 30 have a similar scope.

According to the office action, Phelps discloses a stent having a main body with a plurality of cells and flared ends with predefined bend locations. (Emphasis added) The end structure includes a plurality of cantilever members connected at the bend location (see for example FIG. 8).

However, Phelps’s structure and the location of the bends in FIG. 8 of Phelps make it very clear that the cantilever members do not bend at predefined bend

locations, but rather somewhere along their length. They are flared out by using a dumbbell-shaped balloon 14 to accommodate the anatomy of the vessel(s). For example, the cantilever members bend closer to their free end in the coronary artery CA than in the left ventricle LV, where they bend closer to their attachment point to the stent's main body. Phelps therefore fails to disclose or suggest the claimed predefined bend locations.

As acknowledged in the office action, Phelps fails to teach or suggest the use of notches or, for that matter, of "predefined bend location having a reduced radial wall thickness at the bend location" to facilitate flaring of the end structure (cantilever members) relative to the main body. More particularly, while Phelps' flared edges 28 have a gradual outward taper when flared, they do not have a reduced radial wall thickness, which can be obtained, for example, by providing one or more notches at each predefined bend location. The definition of, for example, "radial" wall thickness is clear from the specification and the drawings and indicates the thickness of the transition region between the stent and the cantilever members (the predefined bend location) in comparison to the thickness of either the stent wall or the adjoining cantilever members. As can be seen from the drawings, the width of the transition region measured along the circumference of the stent remains substantially unchanged.

The office action then cites Shanley as disclosing the use of notches for the purpose of bending sections of a stent, wherein the notch sections have a reduced cross sectional area. Applicant disagrees with the examiner's interpretation that Shanley's notches have a reduced cross-section in the radial direction, as defined in relation to the main body (see discussion of "radial" in the previous paragraph). Shanley's notches facilitate expansion of the stent body in the radial direction, which is facilitated by introducing notches in the stent structure, with Shanley's notches providing a reduced wall thickness in the circumferential direction, which is clearly distinct from the claimed radial direction.

In other words, the ductile hinges disclosed by Shanley are constructed to articulate in the circumferential direction, when viewed in cross-section along the longitudinal axis of the stent, to allow radial expansion of the stent without excessive

buckling. A person designing a stent with individual cantilever members flaring radially outwardly, as in the present invention, would not look to Shanley for a solution to this problem, since Shanley solves an entirely different problem and is specifically interested in maintaining a wall thicknesses great enough to be visible on a fluoroscope. (col. 6, lines 13–15).

The claimed radial direction of the reduced cross-section provides clear advantages when the end structure is flared: because the width of a cantilever member is substantially unchanged along the length of a cantilever member across the bend locations, sideways movement of the cantilever member upon flaring is substantially prevented, causing the cantilever member to move from the longitudinal orientation in alignment with the longitudinal axis of the main body to a flared position projecting radially outwardly from the main body only in a radial direction. Shanley's notches are disadvantageously unable to prevent such sideways movement.

The above discussion applies, *mutatis mutandis*, also to independent claims 14, 27 and 30.

Claims 18-22, 27, and 32-33 are rejected under 35 U.S.C. §103(a) as being unpatentable over Bonsignore et al. (U.S. Published Application No. 2004/0186555; hereinafter "Bonsignore") in view of Shanley.

Claim 18, as amended herein, recites a stent with a main body including a plurality of support members defining a plurality of open cells, the support members extending about a circumference of the main body and each defining an undulating pattern having a plurality of peaks and valleys. The stent further includes a plurality of cantilever members adapted to be flared relative to the main body, each of the cantilever members having a first end connected to one of the peaks of the main body and a second opposing free end, and the cantilever members including notches defining a bend location for facilitating flaring of the cantilever members relative to the main body.

Bonsignore discloses in FIG. 7 a stent comprising a main body with a plurality of cells and flared ends. However, contrary to the assertion in the office action, Applicant

failed to identify in Bonsignore's specification any suggestion or mention of predefined bend locations where the cantilever members are connected to the main body. More particularly, as admitted in the office action, Bonsignore fails to disclose notches to facilitate bending.

Combining Bonsignore with Shanley does not cure this deficiency, as has been discussed *supra*. Claim 18 defines a wall thickness of the stent, generally understood as a radial thickness of the support members, which is different from the width of the support members. Shanley does not disclose notches having a reduced wall thickness and does not define a bend location for facilitating flaring of the cantilever members relative to the main body, as recited in claim 18.

The examiner then states that "living hinges" are common means for bending components relative to one another. A living hinge is a thin flexible web of material that joins two rigid bodies together. However, living hinges are typically designed to remain flexible for at least several cycles. The inherent flexibility of living hinges would defeat the purpose of the present invention, namely to ensure secure seating of the flared cantilever members against a blood vessel wall.

Applicants submit that Phelps, Shanley, and Bonsignore, taken either independently and in combination, fail to disclose or suggest the features of independent claims 1, 14, 18, 28, and 30, as amended herein. Further, claims 2, 3, 5-13, and 25, which depend from claim 1, are allowable for at least the same reasons that claim 1 is allowable as well as for their own unique features. Additionally, claims 15-22 and 26, which depend from claim 14, are allowable for at least the same reasons that claim 14 is allowable as well as for their own unique features, and claim 29, which depends from claim 28, is allowable for at least the same reasons that claim 28 is allowable as well as for its own unique features. Accordingly, Applicants request that the § 103 rejections of claims 1-3, 5-22, and 25-31 be withdrawn.

Withdrawal of all rejections and allowance of the pending claims is therefore respectfully requested.

If the Examiner believes a telephone conversation might advance prosecution, the Examiner is invited to call Applicants' undersigned attorney at 617-933-4421.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 02-3038.

Respectfully submitted,

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Date: 2009-06-12

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